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(54) Title: PROCESS FOR PREPARING RALOXIFENE HYDROCHLORIDE

(57) Abstract: Process for preparing raloxifene hydrochloride with a purity greater than 98% and low aluminium content comprising the following stages a) demethylation of 6-methoxy-2-(4-methoxyphenyl)benzo[b]thiophene in pyridine and hydrochloric acid to obtain 6-hydroxy-2-(4-hydroxyphenyl)benzo[b]thiophene in pyridine hydrochloride, b) acetylation of 6-hydroxy-2-(4-hydroxyphenyl)benzo[b]thiophene with an acetylating agent to obtain the corresponding 6-acetoxy-2-(4-acetoxyphenyl)benzo[b]thiophene, c) acylation of 6-acetoxy-2-(4-acetoxyphenyl)benzo[b]thiophene with 4-(2-piperidinoethoxy)benzoylchloride hydrochloride with aluminium trichloride in halogenated solvent to obtain 6-acetoxy-2-(4-acetoxyphenyl)-3-[4-(2-piperidinoethoxy)benzoyl]-benzo[b]thiophene, d) hydrolysis of 6-acetoxy-2-(4-acetoxyphenyl)-3-[4-(2-piperidinoethoxy)benzoyl]benzo[b]thiophene according to the following operating conditions: d1) treatment of 6-acetoxy-2-(4-acetoxyphenyl)-3-[4-(2-piperidinoethoxy)benzoyl]benzo[b]thiophene with alkaline hydroxide in alcohol solvent, d2) acidification of the product obtained in the preceding stage (d1) with a strong acid, to obtain the corresponding raloxifene salt with the strong acid, characterised in that the strong acid used in stage (d2) is concentrated hydrochloric acid.

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